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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,310	10/01/2001	Antonio Nanci	104/50108	8938

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,310

Applicant(s)

NANCI ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-36 is/are pending in the application.
- 4a) Of the above claim(s) 27-36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-18 is/are allowed.
- 6) ☒ Claim(s) 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/18/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 15-36 are pending in the application. Claims 27-36 are withdrawn from consideration for being directed to non-elected subject matter. Claims 15-26 are currently under examination.

This Office Action is in response to the Amendment filed on 2/26/04.

Response to Amendment

The objection to the oath and declaration is withdrawn.

The objection to the specification is withdrawn in light of Applicant's submission of an abstract.

The rejection of claims 4-8 under 35 U.S.C. 112 1st paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claim 7 under 35 U.S.C. 112 2nd paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-3 under 35 U.S.C. 103 (a) is moot in light of Applicant's cancellation of the claims.

Claims 19-26 are rejected under 35 U.S.C. 112 1st paragraph for reasons set forth of the record mailed on 8/26/03 and further discussed below.

Response to Arguments

Election/Restrictions

Applicants request the rejoinder of claims of Group III, IV and V on the ground that all the claims share special technical feature of the claimed in vivo animal model. Applicants argue that this alone is sufficient to show the unity of the invention is present. Applicants further

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indicate that the claims resemble the example in MPEP Annex B, Example 12, in which the unity of invention exists even when additional features are present.

This argument has been fully considered but deemed unpersuasive. The special technical features of Groups III, IV and V differ from the special technical feature of Groups I and II for reasons discussed in the office action mailed on 8/26/03. The method of each group has its own special technical feature based on the purpose of the method and distinct steps, which is not similar to the example 12 given in MPEP Annex B. Therefore, the invention of Groups III, IV and V lack unity with the invention of Groups I and II, and the restriction requirement is maintained.

Newly submitted claims 27-36 are directed to an invention that is independent or distinct from the elected invention for because they belong to Groups III-V based on the original restriction. They lack unity with the invention of claims 15-26 for same reasons set forth of the record mailed on 8/26/03 and discussed above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are rejected for same reasons discussed in the previous office action mailed on , as applied to claims 4-7. In response to this rejection, Applicants argue that evaluation of histological and histomorphometric parameters are clearly within the skill of the art. In addition, Applicants argue that the amended claims are limited to local injection of the test compounds. Applicants therefore conclude that the claimed method is enabled by the instant specification.

This argument has been fully considered but deemed unpersuasive. As discussed in the previous office action, the nature of the invention is methods for screening drugs for a potential bone disease, tissue repair or anticancer compounds. The breadth of the claims is broad because the claims are drawn to method of screening drugs for any type of bone disease, tissue repair and cancer regardless of their origin and cause. The specification provides very limited teaching for such screening method. The claims recite that an increase in anabolic activity or decrease in catabolic activity in the alveolar bone would indicate a compound is useful for bone disease or tissue repair. However, the specification fails to teach what type of bone disease can be treated by a compound that either increases anabolic activity or decreases catabolic activity. In view of the fact that bone diseases encompass many different types of disorder of different causes and different pathological symptoms, whether a drug that increases a single anabolic activity or decreases catabolic activity can treat any type of bone disease is unpredictable. For instance, whether growth hormone, a factor that increases anabolic activity can treat bone carcinoma is unpredictable. Similarly, tissue repair is a process which involves multiple factors. Whether a substance that increases a single anabolic activity can induce tissue repair is unpredictable. In addition, while the parameter of decrease in eruption rate of the mandibular incisor is indicative of decreased cell proliferation, whether an agent that causes such decrease is useful for treating

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any type of cancer is unpredictable. Although the evaluation of histological and histomorphometric parameters of the incisor is well known in the art, one skilled in the art would still have to engage in undue experimentation to find out whether an agent that causes such histological change is indeed a drug for any type of bone disease, tissue repair or anti-cancer agent. Therefore, the claimed methods are not enabled by the instant specification.

Conclusion

Claims 15-18 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 27-36 drawn to an invention nonelected with traverse in the response filed on 6/11/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER